

**REMARKS**

Applicants respectfully request reconsideration of the present case in view of the above amendments and the following remarks.

Claims 18-20, 45, 47, 49, and 51 have been canceled. Claims 1-3, 6-10, 17, 21, 23, 31-34, 37, 44, 46, 48, and 50 have been amended. Claims 54-64 have been added. Claims 1-17, 21-44, 46, 48, 50, and 52-64 are currently pending.

No new matter has been inserted. Support for the amendment of claim 1 can be found at least at claims 1 and 3. Support for the amendment of claim 6 can be found in the specification at least at page 9, lines 13-17. Support for the amendment of claim 17 can be found at least at page 9 of the specification and original claim 17. Support for the amendment of claim 23 can be found in claim 23. Support for the amendment of claims 31-34, 44, 46, 48, and 50 can be found in original claims 31-34, 44, 46, 48, and 50 respectively. Claims 2-3, 7-10, 21, and 37 were simply amended for clarification. Support for new claims 54-56 can be found in original claim 23. Support for new claims 57 and 63 can be found at least at claim 35. Support for new claims 58 and 64 can be found in the specification at least at page 21 and in claim 37. Support for new claims 59 and 60 can be found at least at page 9 and page 20. Support for new claims 61 and 62 can be found at least at page 9 and page 21.

**35 U.S.C. § 112**

Claims 1-4, 6-11 and 17-53 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection.

Applicants have amended claim 1 to eliminate the term “derivative.” Applicants have amended claims 1, 6, 17, 31-34, 44, 46, 48, and 50 to eliminate the term “selected from the group comprising.” Applicants have amended claims 1, 6, 17, 31-34, 44, 46, 48, and 50 to eliminate the term “e.g.”. Applicants assert that there is now proper antecedent basis for solamargine and solasonine. Claims 6, 17, and 44 no longer refer to structural

formula (I). Claims 45, 47, 49, and 51 have been canceled. Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 102(b) & § 103(a)

Claims 1-53 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over Australian Patent No. AU-B-57853/80 (Cham et al.), WO 91/10743 (Cham et al.), or WO 00/61153 (Cham). Applicants respectfully traverse this rejection.

The present invention, as claimed, is based on the surprising discovery that compositions comprising a combination of two glycoalkaloids in predetermined ratios have enhanced activity relative to the glycoalkaloids alone. The compositions of the present invention are also improved relative to other more complex prior art compositions such as BEC that contain unnecessary constituents.

AU 57853/80 (Cham et al.)

AU 57853/80 (Cham et al.) describes the preparation of an extract from *Solanum sodomeum* (referred to BEC-001), a cream formulation containing the extract, the use of BEC-001 to treat sarcoma in mice and some anecdotal evidence of the use of BEC-001 to treat skin cancer. Figure 1 of AU 57853/80 clearly shows that BEC-001 is a relatively crude extract comprising 4 main components: (i) mono and diglycoside forms of solasodine; (ii) solasodine (an aglucone); (iii) solamargine; and (iv) solasonine.

In sharp contrast, the claims of the present invention are directed to a composition comprising a particular ratio of two triglycoside glycoalkaloids, on the proviso that when the glycoalkaloids are solamargine and solasonine they are isolated (*i.e.* essentially free of mono and diglycosides – see page 7 of the current application). There is no data in AU 57853/80 that would lead a skilled person to combine the glycoalkaloids in the manner described and claimed in the present application. Accordingly, AU 57853/80 does not teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64. Applicants respectfully request that this rejection be withdrawn.

WO 00/61153 (Cham)

WO 00/61153 (Cham) discloses that free sugars (principally rhamnose) in BEC that are formed from the degradation of glycoalkaloids therein can inhibit the activity of BEC. The examples of WO 00/61153 describe the preparation of BEC that is then “washed” using solvent extractions to improve its activity. Importantly, the washed BEC compositions in WO 00/61153 include the mono and diglycoside forms of solamargine and solasonine (see examples 1 and 5 therein).

In contrast, the claims of the present invention are directed to a composition comprising a particular ratio of two triglycoside glycoalkaloids, on the proviso that when the glycoalkaloids are solamargine and solasonine they are isolated (*i.e.* essentially free of mono and diglycosides – see page 7 of the current application). Again, there is no data in WO 00/61153 that would lead a skilled person to combine the glycoalkaloids in the manner described and claimed in the present application. Accordingly, WO 00/61153 does not teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64. Applicants respectfully request that this rejection be withdrawn.

WO 91/10743 (Cham et al.)

WO 91/10743 describes the results of a number of tests on cell lines and sperm exposed to (i) solamargine alone, (ii) solasonine alone, (iii) a mixture of mono and diglycosides alone or (iv) BEC (a mixture of solasonine, solamargine, free sugars and mono and diglycosides) see Tables 1-7 and Figures 1-10 of WO 91/10743.

As discussed above, the claims of the present invention are directed to a composition comprising a particular ratio of two triglycoside glycoalkaloids, on the proviso that when the glycoalkaloids are solamargine and solasonine they are isolated (*i.e.* essentially free of mono and diglycosides – see page 7 of the current application). There is no data in WO 91/10743 that would lead a skilled person to combine the glycoalkaloids in the manner described and claimed in the present application. Accordingly, WO 91/10743 does not teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64. Applicants respectfully request that this rejection be withdrawn.

S/N 10/607,890

**Summary**

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date

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